

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of claims:

Claim 1. (Currently amended) A pharmaceutical composition for topical administration, said composition consisting of:

at least 5% by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 by volume;

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises ~~one or more polyhydric alcohols~~ propylene glycol, the propylene glycol is ~~one or more polyhydric alcohols~~ are present in an amount of less than 10% by weight;

optionally one or more penetration agents selected from the group consisting

of ~~an alcohol~~ dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a propellant, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, an oil component, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive,

wherein the final product of the pharmaceutical composition is selected from the group consisting of a solution, lotion, ointment, mousse, a foam that breaks with shear, spray, aerosol, shampoo, conditioner, gel, cream and paste.

Claim 2. (Currently amended) The pharmaceutical composition according to claim ~~Claim~~ 1, wherein the acid is present in an amount sufficient to provide an apparent pH to the composition of approximately 7.0 or less.

Claim 3. (Previously presented) The pharmaceutical composition according to claim 1, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the pharmaceutical composition.

Claim 4. (Previously presented) The pharmaceutical composition according to claim 3, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claim 5. (Cancelled)

Claim 6. (Currently amended) The pharmaceutical composition according to claim ~~Claim~~ 2, wherein the acid provides to the composition an apparent pH in the range of approximately 5.0 to 7.0.

Claim 7. (Cancelled)

Claim 8. (Currently amended) The pharmaceutical composition according to claim ~~Claim~~-2, wherein the acid is acetic acid or lactic acid.

Claim 9-11. (Cancelled)

Claim 12. (Currently amended) The pharmaceutical composition according to claim ~~Claim~~ 1, wherein the water is present in an amount no greater than approximately 60% by weight based on the total weight of the composition.

Claim 13. (Currently amended) The pharmaceutical composition according to claim
~~Claim~~ 1, wherein the co-solvent is an alkylene glycol.

Claim 14. (Previously presented) The pharmaceutical composition according to
claim 13, wherein the alkylene glycol is selected from one or more of the group
consisting of glycerol, 1,3-butylene glycol and propylene glycol.

Claim 15. (Currently amended) The pharmaceutical composition according to claim
~~Claim~~ 1, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 16. (Currently amended) The pharmaceutical composition according to claim
~~Claim~~ 1, wherein the acid is present in an amount equal to or greater than the
amount of the minoxidil in Normal amounts.

Claims 17-18. (Canceled)

Claim 19. (Currently amended) The pharmaceutical composition according to claim
~~Claim~~ 1, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 20. (Currently amended) The pharmaceutical composition according to claim
~~Claim~~ 1, wherein the minoxidil or the minoxidil salt is present in an amount of from
at least 5 to 25% by weight, based on the total weight of the composition.

Claim 21. (Currently amended) A method for the treatment of hair loss and related
indications in humans, comprising the steps of:

providing a pharmaceutical composition, consisting of

at least 5% by weight, based on the total weight of the
composition, of minoxidil or a pharmaceutically acceptable minoxidil
salt selected from the group consisting of minoxidil acetate, minoxidil
citrate, minoxidil succinate, minoxidil benzoate, minoxidil
hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil
lactate;

an acid in an amount to substantially completely solubilize the
minoxidil or the pharmaceutically acceptable minoxidil salt;

a solvent of water and a lower alcohol wherein the ratio of
water to alcohol is in a range of approximately 9:1 to 1:9 by volume;

a co-solvent selected from one or more of the group consisting
of aromatic alcohols and polyhydric alcohols, wherein when the co-
solvent comprises ~~one or more polyhydric alcohols~~ propylene glycol,
the propylene glycol is ~~one or more polyhydric alcohols~~ are present in

an amount of less than 10% by weight;

optionally one or more penetration agents selected from the group consisting of ~~an alcohol~~ dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a propellant, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, an oil component, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive, and

applying topically to the human scalp a therapeutically effective amount of the pharmaceutical composition.

Claim 22. (Cancelled)

Claim 23. (Currently amended) The method according to claim ~~Claim~~ 21, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 24. (Previously presented) The method according to claim 21, wherein the minoxidil or the pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the composition.

Claim 25. (Cancelled)

Claim 26. (Previously presented) The pharmaceutical composition according to claim 1, wherein the lower alcohol is ethanol.

Claims 27-28. (Cancelled)

Claim 29. (Previously presented) The pharmaceutical composition according to claim 26, wherein the ratio of water to ethanol is approximately 1:1 to 1:3 by volume.

Claim 30 (Currently amended). An aerosol pharmaceutical composition for topical administration, said pharmaceutical composition consisting of:

at least 5% or greater by weight, based on the total weight of the composition, of minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt,

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 by volume;

~~a higher alcohol and a stabilizer;~~

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises ~~one or more polyhydric alcohols~~ propylene glycol, the propylene glycol is ~~one or more polyhydric alcohols~~ are present in an amount of less than 10% by weight;

an antioxidant;

a propellant; ~~and~~

optionally one or more penetration agents selected from the group consisting of ~~an alcohol~~ dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, azone, N-methyl pyrrolidone, a bile salt, urea, and mixtures thereof~~[[,]]~~ ; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a propellant, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, an oil component, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive,

wherein the final product of the aerosol formulation is a foam or a mousse.

Claim 31. (Previously presented) The pharmaceutical composition according to claim 30, wherein the co-solvent is a polyhydric alcohol.

Claim 32. (Previously presented) The pharmaceutical composition according to claim 31, wherein the co-solvent is selected from glycerol, 1,3-butylene glycol and propylene glycol.

Claim 33. (Previously presented) The pharmaceutical composition according to claim 32, wherein the co-solvent is glycerol.

Claims 34.-35. (Cancelled)

Claim 36. (Previously presented) The pharmaceutical composition according to claim 30, wherein the acid is lactic acid.

Claim 37. (Previously presented) The pharmaceutical composition according to claim 30, wherein the higher alcohol is a member selected from the group consisting of cetyl alcohol, stearyl alcohol and combinations thereof.

Claim 38. (Previously presented) The pharmaceutical composition according to claim 30, wherein the stabilizer is Polysorbate 60.

Claim 39. (Previously presented) The pharmaceutical composition according to claim 30, wherein the composition is homogenous.

Claim 40. (Previously presented). The pharmaceutical composition according to claim 30, wherein the lower alcohol is ethanol.

Claims 41.-42. (Cancelled)

Claim 43. (Previously presented) The pharmaceutical composition according to claim 40, wherein the ratio of water to ethanol is approximately 1:1 to 1:3 by volume.

Claim 44. (Previously presented) A method for the treatment of hair loss and related indications in humans, comprising applying topically to the human scalp a therapeutically effective amount of the pharmaceutical composition according to claim 30, to treat hair loss and related indications.

Claims 45.-111. (Cancelled)

Claim 112. (Currently amended) A pharmaceutical composition for topical administration, said composition consisting of:

at least 5% by weight, based on the total weight of the composition, of

minoxidil or a pharmaceutically acceptable minoxidil salt selected from the group consisting of minoxidil acetate, minoxidil citrate, minoxidil succinate, minoxidil benzoate, minoxidil hydrochloride, minoxidil sulphate, minoxidil phosphate, and minoxidil lactate;

an acid in an amount to substantially completely solubilize the minoxidil or the pharmaceutically acceptable minoxidil salt,

a solvent of water and a lower alcohol wherein the ratio of water to alcohol is in a range of approximately 9:1 to 1:9 by volume;

a co-solvent selected from one or more of the group consisting of aromatic alcohols and polyhydric alcohols, wherein when the co-solvent comprises ~~one or more polyhydric alcohols~~ propylene glycol, the propylene glycol is ~~one or more polyhydric alcohols~~ are present in an amount of less than 10% by weight;

one or more penetration agents selected from the group consisting of ~~an alcohol~~ dodecanol, oleyl alcohol, an amine, a carboxylic acid, an ester, an azone, N-methyl pyrrolidone, a bile salt and urea; and

optionally one or more excipients selected from the group consisting of a higher alcohol, a vitamin, a preservative, a buffer, a stabilizer, a propellant, a hair generating agent, an antibacterial agent, a refrigerant, an amino acid, an oil component, a perfume, an antioxidant, a UV absorber, a dye, a humectant, a thickener, a gelling agent, and a color additive,

wherein the final product of the pharmaceutical composition is selected from

the group consisting of a solution, lotion, ointment, mousse, a foam that breaks with shear, spray, aerosol, shampoo, conditioner, gel, cream and paste.

Claim 113. (Cancelled)

Claim 114. (Currently amended) The pharmaceutical composition according to claim 112, wherein the penetration agent is selected from the group consisting of dodecanol ~~alcohol~~ and oleyl alcohol.

Claims 115.-117. (Cancelled)

Claim 118. (Previously presented) The pharmaceutical composition according to claim 112, wherein the acid is added in an amount sufficient to provide an apparent pH to the composition of approximately 7.0 or less.

Claim 119. (Previously presented) The pharmaceutical composition according to claim 112, wherein the minoxidil or pharmaceutically acceptable minoxidil salt is present in an amount of from at least 5 to 25% by weight, based on the total weight of the pharmaceutical composition.

Claim 120. (Previously presented) The pharmaceutical composition according to claim 119, wherein the minoxidil or pharmaceutically acceptable minoxidil salt is present in an amount of from 7.5 to 12% by weight, based on the total weight of the pharmaceutical composition.

Claim 121. (Previously presented) The pharmaceutical composition according to claim 118, wherein the acid provides to the composition an apparent pH in the range of approximately 5.0 to 7.0.

Claim 122. (Previously presented) The pharmaceutical composition according to claim 118, wherein the acid is acetic or lactic acid.

Claim 123. (Previously presented) The pharmaceutical composition according to claim 122, wherein the acid is lactic acid.

Claim 124. (Previously presented) The pharmaceutical composition according to claim 122, wherein the acid is acetic acid.

Claim 125. (Previously presented) The pharmaceutical composition according to claim 112, wherein the lower alcohol is ethanol.

Claim 126.-127. (Canceled)

Claim 128. (Previously presented) The method according to claim 125, wherein the ratio of water to ethanol is approximately 1:1 to 1:3 by volume.

Claims 129.-130 (Cancelled)

Claim 131. (Previously presented) The pharmaceutical composition according to claim 112, wherein the water is present in an amount no greater than approximately 60% by weight based on the total weight of the composition.

Claim 132. (Previously presented) The pharmaceutical composition according to claim 112, wherein the co-solvent is an alkylene glycol.

Claim 133. (Previously presented) The pharmaceutical composition according to claim 132, wherein the alkylene glycol is selected from one or more of the group consisting of glycerol, 1,3-butylene glycol and propylene glycol.

Claim 134. (Cancelled)

Claim 135. (Previously presented) The pharmaceutical composition according to claim 112, wherein the acid is present at a level that provides at least 0.01 Normal acid.

Claim 136. (Previously presented) The pharmaceutical composition according to claim 112, wherein the acid is present in an amount equal to or greater than the amount of the minoxidil in Normal amounts.

Claim 137. (Previously presented) The pharmaceutical composition according to claim 112, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

Claim 138. (Previously presented) A method for the treatment of hair loss and related indications in humans, comprising applying topically to the human scalp a therapeutically effective amount of the pharmaceutical composition according to claim 112, to treat hair loss and related indications.